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EXAMINER

ROSE, SHEP K

ART UNIT	PAPER NUMBER
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1614

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10 035320

Applicant(s)

BARBARA LAKETAL

Examiner

SKSP ROSE

Group Art Unit

0614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period of Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on 11/04/2002
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 2, 4 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 5, 24 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other \_\_\_\_\_

Office Action Summary

Applicants' November 4, 2002 responsive remarks are not accompanied by any terminal disclaimer and state further that a suitable terminal disclaimer will only be filed upon the notice of allowable subject matter.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The USPTO practice is not to withdraw any obviousness-type double patenting ground of rejection until suitable terminal disclaimers are in fact filed and accepted by the USPTO.

Claims 1-22 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-32 of allowed, now patented, copending Application No. 09/453,383 now US Patent No. 6436369 issued August 20, 2002. Although the conflicting claims are not identical, they are not patentably distinct from each other.

This is an obviousness-type double patenting rejection because the conflicting claims have in fact been patented.

This application is a continuation of allowed (now patented) Application Serial No. 09/453,383, filed December 2, 1999, now U.S. Patent 6436369 with allowed claims 28 to 32 to an antiplaque chewing gum in pellet form comprising a water insoluble portion, a water soluble portion, and a coating on the pellet which comprises an emulsifier, triclosan and a surfactant, with about 1mg to about 6 mg of triclosan included in each piece of gum, and a method for reducing plaque by the step of orally applying said chewing gum to the mouth, raising an issue of obviousness-type double patenting of claim 6 to 14, 16 to 22 herein, to the same chewing gum, (claim 17 and 18 imply a chewing gum should be recited in claim 15), also, of claims 1 to 5 and 15 generic thereto.

The claims require, in addition to triclosan, both an emulsifier and a surfactant, but do not require that these be in a coating on the chewing gum. The surfactant is cetylpyridinium chloride in claims 2, 9 and 19. the term of these claims "emulsifier" encompasses species other than set forth in the specification on page 6, lines 27-28. "Emulsifiers may include lecithin, glyceryl monostearate, or other mono and diglycerides. . . ." (There are also softeners), and a typical chewing gum has both (as see page 7, lines 1 to 14).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 to 22 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10 of U.S. Patent No. 6,355,265 in view of Libin (I) U.S. 5,236,699 (details as noted below). It



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Commonly assigned (Wrigley) patents with claims to medicament (broadly) in coatings on chewing gum, namely: U.S. 6,355,265 (claims 1 and 10); U.S. 6,350,480 (claims 10, 12 and 29); U.S. 6,322,806 (claims 1, 10, 19, 28); U.S. 6,290,985 (claims 1, 9, 12, 17, 26) raise an issue of obviousness-type double patenting.

Applicants July 22, 2002 response, after noting that claims 1 to 22 have been rejected on allowed claims 28 to 32 of parent application Serial no. 09/453,383 (now U.S. Patent 6436369) on the ground of non-statutory double patenting, states that a terminal disclaimer" will be filed upon issuance of copending application 09/453,383, which in fact issued August 20, 2002 but the USPTO policy practice and procedure is to reject copending applications for obviousness-type double patenting, and not to wait until they issue as patents.

Applicants July 22, 2002 response notes that claims 1, 2, 4, 5, 15, 19 and 23 have been rejected by Libin (I) U.S. 5,236,699 as anticipated, 35 USC 102 (B), the USPTO Examiner following the MPEP to establish by extrinsic evidence, that Libin describes antiplaque triclosan with cetylpyridinium chloride surfactant as well as with two (2) emulsifying agents: Tweens 20 and Pluronic L64 surfactants, see Merck Index entries for both. The MPEP Sections have been cited to applicant.

Applicants' counsel's responsive remarks, seemingly questions relevance on the MPEP sections permitting the USPTO Examiner to rely on Merck Index to establish the fact that Libin who has two emulsifiers Tween 20 and Pluronic L64 with the same triclosan and the same cetyl pyridinuim chloride surfactant as his antiplaque composition, can be an anticipation, 35 U.S.C. 102.

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Claims 1 to 5, 15, 19, 20, 21, 23 and 24 which do not recite or require any chewing gum, are drawn to antiplaque compositions and oral methods for reducing plaque, wherein the composition comprises (A) triclosan as the antiplaque agent, (B) an emulsifier, and (C) a surfactant, which, in dependent claims 2 and 19 is cetylpyridinium chloride, in dependent claims 3 and 20 there is 3% to 30% triclosan, in dependent claims 4 and 21, there is 0.1 to 10% surfactant, in dependent claim 5 there is (D) water and (E) a solvent for the tri-closan.

Here, the Examiner can properly rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is an anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant.

Claims 1, 2, 4, 5, 15, 19 and 23 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride surfactant a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5 to 2%, a polysorbate pharmaceutical emulsifier and surfactant dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier,

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(according to Merck Index, entry 7722), said combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipates claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

Claims 3, 4, 20, 21 and 24 are rejected as obvious, under 35 U.S.C. 103 over Libin: they differ from Libin (I), in requiring 3% (a) Triclosan instead of 0.05%, and while the chewing gum claims 6-14 and 16-18 are not described, there is clearly only an obvious difference from a mouthwash in Libin in the toothpaste or gel of claim 24.

Claims 6 to 13, 15 to 18 and 22 recite a chewing gum wherein triclosan, an emulsifier and a surfactant are "in a water soluble portion", which only in claim 14, in part, can be a coating of the pellet of the pellet chewing gum recited only in claim 13, and, and only in claim 22 does each piece of gum include 1mg to 6 mg of triclosan. In none of these triclosan chewing gum claims is it recited and required that all of the triclosan, surfactant and emulsifier be a coating on the chewing gum, or that it be a coating on pellet chewing gum, or that there be 1 mg. To 6 mg. of triclosan in a coating on chewing gum, or on pellet chewing gum. Only in claim 13 is the chewing gum in pellet form, and only in claim 14 is the triclosan, in part, in a coating of the pellet with an emulsifier and surfactant.



The term "a water soluble portion" recited in claim 6, in which the triclosan, an emulsifier and surfactant are "included", (although perhaps meant to imply a water soluble coating on the chewing gum) reads on the chewing gum base vehicle, per se, since Hill, U.S. 5380530, at page 8, lines 63 to 68 states the fact that slab chewing gum base is more than 75% water soluble materials, such as sugars, sugar substitutes corn syrup and the like.

Claims 7 to 12 depend on claim 6, and read on triclosan in the chewing gum base of a slab or stick or sheet of chewing gum, which customarily have emulsifiers and surfactants.

Claims 1, 2, 5-7, 9, 13-16 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill U.S. 5,380,530A, 10 January 1995, taken with Libin (I) (details as noted above), it being within the level of skill of the art to replace a single surfactant-emulsifier with a combination of two of them, as described by Libin (I), (details as noted above).

Hill describes an anti-plaque emulsion coating on chewing gum (same as herein) comprising (a) an emulsifying agent (column 10, lines 51-55); (b) Triclosan (same as herein) (column 9, line 58, column 15, line 26, in Example 17, Table II, 0.2 to 1.0%, and claim 2; and (c) cetyl pyridinium chloride (same as herein) (column 15, line 30 and claim 2; and (d) a surfactant, claim 9, column 10, lines 11-50; (TABLE I, "PLURONICS", etc.) and (e) chewing gum plasticizer softening agents which happen to be applicants' "emulsifiers" according to the recitals of this specification at page 6, lines 22-28 and

Example 2 page 10: Hydroxylated lecithin in the Example, lecithin, glycerol monostearate, or other mono or diglycerides, Hill describing applicants' emulsifiers acetylated monoglycerol triacetate, glycerol diacetate, and lecithin, 0.4 to 0.6% at column 19, line 65 to column 20, line 11.

Hill (details as noted above) emulsion coats triclosan on chewing gum (same as herein) and renders obvious (35 U.S.C. § 103) claims 1, 2, 5-7, 9, 13-16, and 19 the rejection being made under 35 U.S.C. § 103, but differs from, and does not explicitly anticipate or describe claims 3, 10, 20 and 22 in the percentage of Triclosan (1% versus 3%), and differs from claims 4, 11 and 21 in not specifying the percentage of surfactant in the anti-plaque Triclosan chewing gum coating, however, clearly, it being within the level of skill of the art to replace equivalent percentages of a single surfactant-emulsifier with percentages of a combination of two of them, as described by Libin (I), (details as noted above), the Examiner relying on Merck Index extrinsic evidence to establish that claim encompassed surfactants of Hill are known as emulsifiers as well.

Hill, according to applicants' counsel's remarks does not anticipate these claims under 35 U.S.C. § 102 because it is argued, herein a single surfactant and emulsifier are employed with Triclosan to emulsion coat the chewing gum, but to interchange equivalent percentages of a combination of a surfactant and an emulsifier to attain the same goal is clearly prima facie obvious 35 U.S.C. § 103.

Hill emulsion coats triclosan and cetylpyridinium chloride (same as herein) onto "slabs" sheets of chewing gum base, (in contrast to onto candy coated gum nuggets

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(col. 9, lines 1 to 15) or placing his claimed emulsions into liquid center chewing gums or into chewing gum base mixes as in Wrigley chewing gums (col. 8, lines 38-68) which are more than 75% water soluble materials such as sugars, sugar substitutes, corn syrup, etc.) Claim 6 herein recites such water-soluble portions, at the chewing gum base, to include the triclosan.

Hill explicitly applies his emulsion coatings of triclosan, and/or cetylpyridinium chloride (same as herein) onto chewing gum in sheet or slab form (column 21, lines 10 to 22, column 22, line 19 to 22, 28, 29, 47, 48 onto a sheet of gum, emulsion coating on the chewing gum sheet, sheet of chewing gum, column 23 lines 1, 2 chewing gum sheet.

The term "chewing gum" in applicants' claims 6 to 12, 16 to 18 and 22 encompasses Hill's preferred enabled examples of slab or sheet "slabs" of chewing gum.

Only in applicants' dependent claims 13 and 14 is the chewing gum defined as in pellet form, and only in dependent claim 14 is the triclosan emulsion chewing gum coating (Same as Hill's), and only in part, a coating of the pellet.

"Pellet" chewing gum may be the non-preferred "costly alternative" to Hill's desired slab forms of chewing gum, set forth by Hill at column 9, lines 1 to 16, in contrast to chewing gum wherein medicament is in a candy coating on a gum nugget or center, commonly called "candy coated gum", but these are clearly contemplated by Hill as encompassed by the triclosan and cetylpyridinium emulsion coating of "chewing gum"

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in claim 2 of Hill, as see column 23, lines 6 to 10, in any desired mg quantity, on a wide range of piece size and shape, "mints", sticks, slabs, lines 45 to 52 modifications are with the scope of the claims.

Claims 1-7, 9-11, 13, 15-17 and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson et al., U.S. 5,487,902A, 30 January 1996, who describe (column 11 line 58 to column 12 line 5) any chewing gum (candy coated "bits" or sticks) with active agents to be chewed for 2 to 30 minutes, said chewing gums including: (a) Triclosan (column 9, line 24; 0.1 to 10% at column 10, line 26 and 0.01 to 30% at column 12, line 53; (b) cetylpyridinium chloride at column 8, lines 54-55; and solubilized with emulsifying solubilizing surfactants "AT LEAST ONE" and "A COMBINATION OF SEVERAL" at column 6, lines 21-22 and claim 12; (c) solubilizers-surfactants (all known and approved for use as emulsifiers) (column 5, line 57 to column 6, line 24, 1% to 10% at column 10, lines 56-57, column 12, line 55 and claim 4; (d) emulsifying active agent solubilizing agents, column 7, lines 8-26, 0 to 12%.

Anderson et al. anticipate claims 1-7, 9-11, 13, 15-17, and 19-21 but does not explicitly specify a weight of 1 mg to 6 mg of Triclosan per piece of gum as in claims 12 and 22, and do not explicitly state to chew the gum three times per day as in claim 18, and beyond chewing gum, do not further describe a mouthwash toothpaste or gel as in claims 23 and 24.

Applicants' counsel's remarks have been considered but are seen to have inadvertently overlooked the terms "AT LEAST ONE" and A COMBINATION OF SEVERAL" (c) solubilizer surfactants known as emulsifiers as well as the (d) emulsifiers

employed by Anderson in chewing gum base with (a) Triclosan and (b) cetylpyridinium chloride, which in the claims herein are neither recited to be in a coating on the gum, or inside the chewing gum base center itself, while applicants' only claimed coating, in claim 14 "IN PART" unfortunately does not recite or require that 100% of the Triclosan is in the pellet coating on the pellet center, there being "NO TRICLOSAN WHATSOEVER" in applicants' described and enabled chewing gum base or gum pellet center as a careful review of the specification will establish to anyone's satisfaction.

The remarks and arguments by applicants' attorney (who has not been qualified as an expert) are not considered to be the opinion of an expert, see In re Schulze 145 USPQ 716"... Argument of counsel cannot take the place of objective evidence ...". They certainly reveal a lack of recognition that claims encompassed surfactants function as emulsifiers. There is no Rule 132 Declaration of any expert by applicants who are considered to be skilled in the art to buttress or to support the argument, which is unsubstantiated. Counsel's remarks have been considered, but are not seen as a substitute for a Rule 132 Declaration of an expert, when technical counsel is arguing → facts. Attorney argument is not evidence, unless it is an admission. See: In re De Blauwe, 222 USPQ 191, 196; Meitzner v. Mindick, 193 USPQ 17, 22, In re Pearson, 181 USPQ 641, 646, In re Lindner, 173 USPQ 356, 358; In re Schalze, 145 USPQ 716, 718; In re Cole, 140 USPQ 230, 233, and In re Walters, 77 USPQ 609, 610. The following arguments have been made in the remarks:

"LIBIN" does not describe the use of an emulsifier ..., "... to overcome the emulsifier element deficiency in Libin ..." In this regard, Libin does not disclose an

emulsifier...” “... Neither Hill nor Anderson discloses the use of a nonionic surfactant as an emulsifier ...”; “... Clearly the Hill and Anderson references do not teach the use of a nonionic surfactant as an emulsifier ...”, “indeed Hill discloses a variety of surfactants but not that such surfactants may also function as an emulsifier”. “Thus combining the teaching of Libin with that of Hill would fail to arrive at applicants’ claimed invention because the required emulsifier element would be missing”.

Applicant’s arguments have been fully considered, but are clearly erroneous. Libin’s Tweens 20 and Pluronics 264 are not only described by Merck Index as emulsifying agents, they are also described by Anderson et al as apt solubilizing surfactants for active agents in chewing gum known to be emulsifiers. Anderson et al describe both of Libin’s surfactant Tweens and Pluronics in Examples as solubilizing surfactants known for use as emulsifiers. Both Hill and Anderson do in fact teach the use of non-ionic surfactants as emulsifiers. See: In Hill, column 10 line 11, suitable surfactants and emulsifiers for use in the present emulsion coating for gum include: (“Tweens”) at lines 49 and 50, line 23 to 25 (polyoxyethylene derivatives of sorbitan esters) (“Pluronics” mentioned at lines 45 to 49), Table I, columns 11 and 12, (both in claim 9 of Hill). Anderson et al teach both of Libin’s Pluronic and Tween surfactants to be known for use as emulsifiers (See column 6, lines 1 to 24 as well as Tweens in Examples 48 to 75, and 100 to 103, 113, 146 Pluronics in Examples 76 to 87, and note both in Anderson et al’s claims 4 and 5.

Applicants' attorney's arguments do not reflect USPTO practice. The remarks include: As previously argued, Libin I fails to disclose the emulsion features of independent Claims 1 and 15. Nowhere does Libin I disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on Libin I where Libin I discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. See, Libin I, Claim 1, col. 1 at lines 53-60. In this regard, Libin I emphasizes solubilizing, not emulsifying triclosan. Moreover, as discussed above the Patent Office is not permitted to expand the meaning of the solubilizer disclosed in Libin I to also mean an emulsifier. It is clear that Libin I is using Tween 20 only as a solubilizer not as an emulsifier. While it is perhaps arguable that Tween 20 is also useful as an emulsifier, the reference clearly does not disclose using it as one. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. As noted above, extrinsic evidence is not allowable to "expand the meaning of terms in a reference".

Applicants' attorney's remarks on Anderson et al in advertently overlook the above noted teaching of Anderson et al to employ solubilizing surfactants known to be useful emulsifiers. It is argued:

In the Office Action, claims 1-7, 9-11, 13, 15-17 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Andersen. The Patent Office essentially asserts that Andersen discloses each and every feature of the rejected claims.

Applicants submit that the Patent Office again incorrectly relies on Andersen as an anticipatory reference. The Examiner's position that " they do not have to state that their surfactants are emulsifiers, if extrinsic evidence (Merck Index) establishes that such encompassed species of nonionic surfactants to be used are emulsifiers." Is clearly contrary to established law. See, Office Action, p. 89. It is argued:

Andersen, like Libin I, requires a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. See, Andersen, Claim 1, col. 10 at line 57-61. Further, Andersen clearly makes a distinction between the uses of an emulsifier as compared to solubilizers. Again, while it might be arguable that these solubilizers may also be emulsifiers, it is clearly not described as so in the Anderson reference. (This argument is contrary to Anderson to use solubilizer known as emulsifiers). Moreover, extrinsic evidence is "not permitted" to expand the meaning of terms in a reference.

The Examiner properly relies on Merck Index as extrinsic evidence showing that those of ordinary skill in that art know that the nonionic Tween and Pluronic surfactants of Libin, Hill and Anderson function as emulsifiers. See MPEP § 2131.01 (d) and MPEP § 2112-2113 for case law on inherency. See: Atlas Powder versus Ireco, 51 USPQ 2d 1943.

The legal basis for an inherency rejection, one that can properly be made under 35 U.S.C. § 102/103, is set forth in MPEP § 2112-2112.02 citing In re Fitzgerald et al., 205 USPQ 594. When the reference discloses all the limitations of a claim except a



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property or function, whether or not the reference inherently possesses properties or renders obvious the claimed invention, there is basis for shifting the burden of proof to applicant. Also, MPEP § 2183-2184, when the reference teaches all the claim limitations except a claimed element, an examiner is not certain whether the element disclosed in the reference is an equivalent to the claimed element and therefore anticipated, or whether the prior art element is an obvious variant of the claimed element.

Here, the Examiner can rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant. These claims are clearly anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride, a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5 to 2%, a polysorbate pharmaceutical emulsifier and surfactant dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier, (according to Merck Index, entry 7722), said

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combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipated claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

In an attempt to advance the prosecution of this application to a more timely issue, the Examiner can properly substantiate in the record the well known fact, as a matter of common knowledge in the art, that the two (2) surfactants of LIBIN (I) function as emulsifiers according to Merck Index. The claims that had been rejected under 35 U.S.C. § N 102/103 on Libin alone on a theory of inherency, based on this well known substantiated fact MPEP § 706.02 (a), 707.07 (f) can properly be rejected either on 35 U.S.C. § 102 or on 35 U.S.C. § 103.

While applicants herein have 100% of the Triclosan and cetylpyridinium chloride in the pellet outer coatings, and 0% of each inside their chewing gum base center, claims 6, 13 and 14 are clearly not commensurate in scope with applicants' disclosed enabled and described invention, but the broadest reasonable interpretation of these claims metes and bounds must be given.

Claim 1 does not recite or even require that --said anti-plaque emulsion comprise a coating of the pellet chewing gum in pellet form--.

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Claim 1 does not define the emulsion as defined in the specification on page 6, lines 22-28 and Example 2 on page 5 as said emulsifier being selected from the Markush group consisting of --hydroxylated lecithin, lecithin, glycerol monostearate, other mono- and diglycerides--. The term "surfactant" in claim 1 clearly encompasses known species of surfactants which function inherently and have been described in the prior art as emulsifiers, by Anderson et al, (as noted above), and by Hill (as noted above).

The Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP § 2112-§2113 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.<

Atlas Powder Co. C. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art ... however, the discovery of a previously unappreciated property of a prior art composition patentably new to the discover. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Mehl/Biophile International Corp. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

Thus viewed as a whole, the Polla disclosure shows that the "natural result flowing from the operation as taught would result in alignment of the laser light over the hair follicle,

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as claimed.” This was true even though Polla did not mention the goal of hair removal. Therefore, the Court held that the ‘192 patent was invalid as anticipated.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

INHERENCY OF METHODS. Ex parte Novitski 26 USPQ 1389 (BPAI 1993)

Meh/Biophile International Corp. V. Milgraum. 52 USPQ2d 1303 (Fed. Cir. 1999)

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 7:30 AM to 6 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

*Shep Rose*  
SHEP K. ROSE  
PRIMARY EXAMINER

Rose/LR  
January 9, 2003